The premier education and advocacy organization for the oncology team

ACCC
Association of Community Cancer Centers

August 20, 2004

BY ELECTRONIC DELIVERY

Jeffrey Shuren, M.D.
Assistant Commissioner for Policy
Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2004S-0233: Solicitation of Comments on Stimulating Innovation in Medical Technologies

Dear Dr. Shuren:

The Association of Community Cancer Centers ("ACCC") appreciates this opportunity to respond to the Department of Health and Human Services' ("HHS") solicitation of comments on stimulating innovation in medical technologies, published in the Federal Register on May 24, 2004.[1] ACCC's members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member

[1] 69 Fed. Reg. 29544.

institutions and organizations treat 45 percent of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60 percent of all U.S. cancer patients.

ACCC is committed to ensuring that cancer patients have access to care, including access to the most appropriate, innovative cancer therapies. Our members are proud to be part of the best cancer care infrastructure in the world. Our providers and facilities provide advanced care to patients in communities all across the nation, giving patients a range of choices regarding their treatment. We facilitate our patients' ability to make informed choices about which therapies to take, which facilities and doctors to use, and whether to participate in clinical trials, based on their particular needs and concerns. It is this ability to choose that drives innovation, inspiring researchers and health care providers to pursue continued improvements in cancer care.

Our members are keenly aware of the roles HHS and its agencies play in cancer care in the United States. All aspects of cancer care – basic research that furthers understanding of cancer and its treatment; review and approval of new therapies; coverage of drugs, biologicals, and other medical services; and development and dissemination of public health messages regarding cancer prevention, screening, and treatment – are shaped by the National Institutes of Health ("NIH"), the Food and Drug Administration ("FDA"), the Centers for Medicare and Medicaid Services ("CMS"), and the Centers for Disease Control and Prevention ("CDC"). Our patients' ability to choose the most appropriate therapies for their cancers depends on these agencies' actions to provide access to quality care.

We therefore appreciate and share HHS' concern with ensuring that that these agencies stimulate innovation in medical technologies. Our comments address each of the seven questions posed in the Federal Register notice.

1. What strategies and approaches could HHS implement to accelerate the development and application of new medical technologies?

The essential question regarding any proposal to stimulate innovation is: "will this proposal expand patient access to improved care?" ACCC strongly believes that patient access to innovative therapeutic options is critical to the continued advancement of cancer care. HHS currently does much to ensure patient access, including supporting participation in clinical trials, approving new drugs and biologicals at increasingly rapid rates, and covering a wide array of therapies under the Medicare program. ACCC supports a strategy of maintaining HHS' existing programs that encourage access and innovation. We urge HHS to dedicate

its limited resources to make truly needed improvements in the cancer care infrastructure, as outlined in depth below.

2. How can HHS help its agencies to work together more effectively to eliminate obstacles to development of medical technologies?

Each of the HHS agencies makes significant contributions to improving cancer care, but the other agencies often fail to recognize those contributions in a timely manner. For example, because CMS requires six months of marketing data before it will begin the coding process, new technologies do not receive codes until 15-27 months after the FDA approval, delaying coverage, data collection, and efficient claims processing for the therapy. These delays complicate health care providers' efforts to be reimbursed which, in turn, discourages them from offering innovative therapies to their patients. We believe CMS should time the process to coincide with FDA approval, eliminate the requirement of six months of marketing data, and accept new code applications on a quarterly basis, to remedy this obstacle.

We recommend that HHS encourage communication among its agencies about new technology developments. Improved communication will help all agencies efficiently recognize new technologies as they are developed and will promote faster access to new treatment options. For example, we recommend that HHS:

- Encourage FDA to notify CMS of drugs likely to be approved in the next six months, thereby alerting CMS of the need to prepare Medicare policies and coding decisions associated with FDA marketing approval of these new therapies;
- Support CDC and CMS collaboration regarding the development, promotion, and coverage of new cancer screening guidelines and tests; and
- Promote NIH, FDA, and CDC collaboration to create enhanced drug development, safety, and effectiveness "toolkits" as discussed in the FDA's Challenge and Opportunity on the Critical Path to New Medical Products (March 2004).

3. Methods for HHS scientific and regulatory agencies work more effectively with CMS to eliminate obstacles to development.

ACCC is very concerned about the obstacles that currently discourage participation in clinical trials. Clinical trials are essential to turning hope into reality, both for the patients who directly benefit from participation and for the patients who will benefit from the information generated from the clinical trials.

We applaud the measures already in place at NIH and CMS to stimulate participation in clinical trials, such as the www.ClinicalTrials.gov website, Medicare's national coverage decision regarding coverage of routine costs associated with many clinical trials and its goal of promoting participation in clinical trials, and development of a central institutional review board ("CIRB") that alleviates many of the administrative burdens on local investigators. Even with these efforts, though, there is more work to do to expand access to clinical trials, particularly among the Medicare population.

We urge the HHS scientific and regulatory agencies to work with CMS to promote clinical trials through methods such as:

- Encouraging NIH and CMS cooperation to create a simplified and standardized process for enrollment in clinical trials;
- Using CMS' regular notices to educate providers about NIH programs, such as the CIRB, that support smaller facilities' participation in clinical trials;
- Supporting NIH and FDA cooperation to develop programs that further encourage Medicare beneficiary participation in clinical trials and standardize agency recognition of the Medicare patient population's unique needs in clinical trial design; and
- Helping CMS develop criteria identifying clinical trials where Medicare will cover routine beneficiary costs during participation

4. Forums to survey constituents about obstacles to innovation.

ACCC greatly appreciates this opportunity to comment on the obstacles to innovation, and we encourage HHS to seek more input on these problems from a wider audience. We suggest that HHS hold public meetings in locations across the country to allow a broad spectrum of patients, providers, researchers, non-governmental agencies, and manufacturers to comment. We also recommend that HHS promote these opportunities in the local media and on its website, rather than solely in the Federal Register.

5. Methods to optimize the portability of information between HHS agencies.

Although we are pleased to offer comments on many areas in which HHS can improve its efforts to stimulate innovation, we caution HHS against tampering with current procedures that work well. In particular, we urge HHS to recognize and protect the proprietary nature of data submitted to the FDA during the approval process for new technologies. Researchers and manufacturers have confidence that information they submit will be kept confidential and will not be

used for unauthorized purposes. They will be reluctant to provide sensitive data if this confidentiality is not preserved. Furthermore, the information submitted to satisfy FDA approval requirements is not intended and may not be suitable for or relevant in CMS' coverage determination process. As CMS itself has explained, FDA approval involves review of different data, for different purposes, than CMS requires for its coverage decisions. Although we understand HHS' interest in sharing data across agencies, we believe any benefit of sharing this type of information between the FDA and CMS would be outweighed by the resulting negative effect on innovation.

6. a. Policies and programs that effectively spur innovation.

As we noted earlier, the HHS agencies profoundly shape the environment of cancer care in the United States and strongly affect innovation of new therapies. We have mentioned several areas in which HHS agencies have successfully expanded patients' ability to choose among effective therapeutic options, and we encourage HHS to strengthen and expand these programs by:

- Promoting NIH's investment in research to advance understanding of the causes and treatment of cancer and its patient education programs, such as the MedlinePlus website and www.ClinicalTrials.gov, that help patients understand their conditions and treatment options;
- Continuing to improve FDA approval times and supporting its plan for a cancer drug center; and
- Continuing CMS' provision regarding new technology add-on payments and coverage of off-label uses for FDA-approved drugs and biologicals.

ACCC also commends HHS' development of a 10-year plan to build a new health information infrastructure that will improve the quality of care, facilitate research, and reduce health care costs over time. The "Decade of Health Information Technology" report correctly notes that providers will not be able to adopt this new technology without financial support from the government. We encourage HHS and CMS to work with providers to develop effective incentives and payment systems to reimburse physicians for their information technology costs.

b. Policies and programs that pose obstacles to innovation.

ACCC's members have learned from their experience as Medicare providers that many CMS policies and programs pose obstacles to innovation. Of primary importance to our members are CMS' coverage, coding, and reimbursement policies. Continued innovation depends on timely patient access to new therapies.

Patient access, in turn, depends on Medicare's coverage decisions, timely and appropriate coding that allows providers to efficiently file claims for the technology, and reimbursement rates that reimburse providers adequately for providing newer, more advanced therapies. If patients are denied access to advanced therapies because of Medicare's coverage, coding, or reimbursement decisions, the creators of these therapies will be discouraged from pursuing further advancements.

ACCC has addressed many of our concerns about CMS's policies in our prior comments on Medicare payment rules, and we would be happy to discuss those comments further with HHS. To briefly summarize our concerns, we provide the following examples of CMS policies that discourage innovation.

- CMS' slow coding process delays recognition of new technologies in Medicare's reimbursement systems, discouraging providers from using these technologies.
- CMS's excessively narrow and erroneous application of new technology add-on payment criteria under the hospital inpatient and outpatient prospective payment systems results in very few new technologies actually benefiting from these policies.
- CMS' failure to adequately reimburse providers for social work, nutritional counseling, pharmacy services, and other costs incurred in delivering high quality, effective cancer care limits patients' access to these important services. Some of these services are critical to maximizing the effectiveness of innovative drug and biological therapies and other new technologies.
- Medicare's reimbursement rates fail to keep up with inflation, preventing our members from investing in medical research and innovations such as electronic medical record systems that are indispensable to improving the quality of patient care and reducing future health care expenditures.
- CMS' failure to issue the criteria for identifying clinical trials that qualify for coverage but are not in the limited categories automatically deemed as covered.

For clinical trials that are included in the current coverage policy, CMS should do more to encourage patient participation. Patients who participate in clinical trials may worry that they will have higher out-of-pocket costs, such as copayments, because they receive more medications and services than they would if they chose standard therapy. Patients in Medicare Advantage plans are especially likely to be concerned about higher costs because their clinical trial costs are paid under Part B, which typically imposes greater copayments than their managed care plans do.

Patient anxiety about these extra costs serve as a disincentive to participate in clinical trials, but CMS could easily allay these concerns. Several studies have shown that clinical trials are no more costly than conventional care, and trial sponsors typically cover costs not paid by Medicare or other insurers. A policy that seeks to encourage innovation should reassure patients that participating in clinical trials will not increase their costs, so financial worries need not prevent patients from helping themselves and others. We recommend that CMS increase its efforts to educate patients about the costs and benefits of participating in clinical trials.

ACCC also is concerned that health care providers are discouraged from participating in clinical trials by Medicare's inadequate reimbursement rates. Medicare's declining reimbursement rates for physician services and hospital care leave physicians and hospitals with tighter operating margins and decreased ability to absorb the extra costs of treating patients in clinical trials, especially for those patients in control groups whose costs typically are not covered by trial sponsors. Patients in clinical trials often require more intense services, such as extended physician visits, yet Medicare has no methods of compensating providers for those costs. Instead, falling reimbursement rates require physicians and institutions to treat patients quickly which does not allow room for physicians to offer extended examinations and data collection tasks that are required for clinical trial participation. We urge CMS to recognize these costs and provide appropriate reimbursement to physicians and hospitals.

In brief, the following summarizes our concerns and recommendations regarding Medicare coverage of the routine costs associated with clinical trials:

- CMS' failure to fully implement its clinical trial coverage policy after a four year wait for criteria to identify qualifying trials limits Medicare beneficiary participation. ACCC recommends that CMS issue these criteria immediately.
- CMS' clinical trial reimbursement policy may discourage patients from participating out of fear that they would be liable for additional out-of-pocket costs. ACCC recommends that CMS relieve patients' anxiety by providing clear guidance about their out-of-pocket costs.
- Inadequate Medicare reimbursement rates discourage physicians and hospitals from participating in clinical trials. ACCC recommends that CMS adjust payment rates to reimburse providers appropriately for all the important services they provide.

7. Role to be played by nongovernmental partners in assisting the federal government in this process.

Finally, ACCC encourages HHS to include nongovernmental entities among the stakeholders as it considers methods of stimulating innovations. Many of these entities have already developed methods of promoting improved access to care, and we urge HHS to avoid duplicating their work. To give just one example, the National Comprehensive Cancer Network ("NCCN"), an alliance of 19 of the world's leading cancer centers, has developed treatment guidelines to help patients and physicians choose the best treatment options for their particular conditions. The NCCN would be a valuable participant in any discussions about policies to stimulate innovation and expand patient choices.

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ACCC appreciates the opportunity to offer these comments and looks forward to continuing to work cooperatively with HHS to address these important issues. Please feel free to contact our staff person, Deborah Walter, at (301) 984-9496, ext. 221, if you have any questions or if ACCC can be of further assistance. Thank you for your leadership to the very important issues raised by this notice.

Respectfully submitted,

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